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The HIV and Drug Abuse Prevention Research Ethics Training Institute: Training Early-Career Scientists to Conduct Research on Research Ethics

Celia B. Fisher[1] and Elizabeth Yuko[1]

Abstract

The responsible conduct of HIV/drug abuse prevention research requires investigators with both the knowledge of and ability to generate empirical data that can enhance global ethical practices and policies. This article describes a multidisciplinary program offering early-career professionals a 2-year intensive summer curriculum along with funding to conduct a mentored research study on a wide variety of HIV/drug abuse research ethics topics. Now in its fifth year, the program has admitted 29 trainees who have to date demonstrated increased knowledge of research ethics, produced 17 peer-reviewed publications, 46 professional presentations, and submitted or been awarded five related federal grants. The institute also hosts a global information platform providing general and HIV/drug abuse relevant research ethics educational and research resources that have had more than 38,800 unique visitors from more than 150 countries.

Keywords

ethics, training, HIV, drug abuse, community-based research, evidence-based ethics

HIV/AIDS continues to take a tremendous toll on people who use drugs domestically and internationally. The evolving nature of the HIV pandemic, dynamic shifts in drug use patterns, criminalization of drug use, and other HIV risk behaviors, along with the use of new technologies and other rapid advances in treatment and prevention, create continuously changing ethical challenges for HIV research involving people who use and abuse drugs and other vulnerable populations (Loue & Pike, 2010). Advocates for the human rights of drug users and international organizations championing the rights of vulnerable populations affected by the HIV pandemic have found common cause in urging investigators, funders, and ethics review committees to give greater attention to the development of HIV prevention research ethics policies and practices that are sensitive to the discrimination, stigmatization, police harassment, and social marginalization experienced by persons who use drugs (Centers for Disease Control and Prevention [CDC], 2013; Deren et al., 2011; Des Jarlais et al., 2013; Fisher, 2004; Joint United Nations Programme on HIV/AIDS [UNAIDS], 2013). Addressing such challenges requires investigators with both knowledge of and ability to generate empirical data that can enhance practices and policies directed at protecting the rights and welfare of participants in HIV/drug abuse prevention studies. There are a few pioneering graduate and postgraduate programs in the medical, public health, and behavioral sciences providing formal education in research ethics, but to date, none include specific training in the skills required to design empirical studies on ethics-in-science practices (Coats, Stafford, Thompson, Javois, & Goodman, 2015; Crump, Sugarman, & the Working Group on Ethics Guidelines for Global Health Training, 2010; DeBruin et al., 2007; DuBois, Schilling, Heitman, Steneck, & Kon, 2010; Lee, Wright, & Semaan, 2013; Loue & Loff, 2013; Matar, Garner, Millum, Sina, & Silverman, 2014; Silverman, Strosberg, Luna, Philpott, & Hemmerle, 2013; Strosberg, Gefenas, Loue, & Philpott, 2013). To date, the Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute (RETI) is the only program to address these vital training and global information needs.

In 2011, The Fordham University Center for Ethics Education was awarded funding from the National Institute on Drug Abuse (NIDA Grant R25DA031608; principal investigator: C. B. Fisher) to launch the multidisciplinary RETI. The program's aims are to (a) increase early-career

[1]Fordham University, Bronx, NY, USA

Corresponding Author:
Celia B. Fisher, Center for Ethics Education, Fordham University, Dealy Hall, 441 East Fordham Road, Bronx, NY 10458, USA.
Email: Fisher@fordham.edu

prevention scientists' knowledge of and competencies to address key ethical issues in HIV and drug abuse prevention research; (b) enhance investigators' capacity to ethically engage participants and communities in the construction of participant protections; (c) provide training, mentorship, and funding to generate empirical data to inform HIV prevention research practices and policies; and (d) create and sustain a global online information network to provide investigators, institutional review boards (IRBs), educators, and community members continuously updated resources on HIV/drug abuse research ethics issues, empirical tools, and evidence-based practices. In this article, we describe the program's organizational structure, recruitment process and admitted institute trainees, training description and objectives, program evaluation, and future impact.

Organizational Structure

The organizational structure of the RETI includes a year-round staff, a multidisciplinary advisory committee (MAC), and a nationally representative faculty.

RETI Staff

The RETI director is responsible for oversight of all institute activities including curriculum development, design of evaluation materials, chairing of advisory committee meetings, faculty selection and guidance, all phases of trainees' mentored research projects (MRPs), and trainees' career development during and following their 2-year activities. The director is assisted by the program administrator who is responsible for the day-to-day activities of advertising, recruitment, scheduling institute activities, setting up advisory board meetings and conference calls, ensuring timely submission of mentees' MRP proposals, IRB applications, progress reports, analysis of evaluation measures, and has primary responsibility for the online global informational resource network. The RETI also benefits from having a budget administrator responsible for budget approval of each MRP, contracts with each mentee's home institution, monitoring mentee use of funds, and appropriate handling of invoices.

MAC

The RETI benefits from a 10-member MAC composed of scientists, educators, clinicians, IRB members, and bioethicists. Through annual fall and spring in-person meetings and online consultation throughout the year, committee members are responsible for the oversight of recruitment and selection procedures, as well as to assist in tailoring curricula to each cohort's specific needs, assignment of faculty mentors, evaluation of individual trainee progress on their MRP, and a biannual review of outcome measures and recommendations for program modification, when appropriate.

Faculty

The RETI has attracted leading scholars in HIV and drug abuse research and research ethics from institutions across the United States. The original 25-member multidisciplinary faculty, which has now grown to 32 members, includes internationally recognized leaders in the development and implementation of federal regulations and guidance related to HIV/drug abuse research; empirical research on research ethics (ERRE) methodology and education; developmental and psychological influences of HIV and drug abuse on informed consent; IRB review; social and legal risks of HIV/drug abuse research involving men who have sex with men (MSM), female sex workers (FSWs), and prisoners; and multicultural and community engaged research. Many have extensive experience conducting research globally throughout Africa, Southeast Asia, Central and Eastern Europe, and Central and South America.

Institute Trainees

Recruitment of qualified applicants is facilitated through a multipronged plan to draw trainees from a broad range of disciplines, including medicine, the social and behavioral sciences, nursing, public health, and social work. Over the past 4 years, the RETI has received a total of 116 applications from which the MAC selected 29 (averaging 6-8 a year) highly accomplished young scientists with advanced degrees in public health, epidemiology, psychology, anthropology, law, and medicine.

Recruitment, Applicant Evaluation, and Admission

The program strives to achieve trainee disciplinary, gender, racial/ethnic, and geographic diversity through intensive recruitment strategies. Calls for applications are sent to principal investigators identified through the National Institutes of Health (NIH) Research Portfolio Reporting Tool and to directors of doctoral and postdoctoral training programs in and outside the United States. The RETI also advertises on general and diversity-focused professional science organization listservs (e.g., American Public Health Association, Society for Medical Anthropology, the HIV Prevention Trials Network, Association of Black Psychologists, The National Hispanic Network on Drug Abuse, and National Minority AIDS Council).

To apply for the RETI program, early-career investigators must have (a) received a medical or doctoral degree in the past 10 years in social behavioral, public health, or related fields; (b) demonstrated scholarship in HIV and drug abuse prevention research; and (c) met the geographical requirements to apply for NIH funding. Applicants must submit their current curriculum vitae, an official transcript

from their highest completed degree, and two letters of recommendation. Of the two required letters of recommendation, one must be from a department chair or postdoctoral supervisor who can confirm that the trainee's institution is supportive of his or her participation in the 2-year program. Applicants must also complete online essays describing (a) their research experience and current HIV/drug abuse research projects; (b) training, experience, and interest in research ethics issues (as expected, outside the Collaborative Institutional Training Initiative (CITI) online training, few have formal education in research ethics); (c) preliminary ideas for a MRP; and (d) the feasibility of implementing the MRP based on their current research projects and access to the proposed population.

Trainees

The 29 trainees accepted into the program (78% female) are highly qualified HIV and drug abuse researchers, with an average of 17 peer-reviewed publications (range = 8-22) at the time of their application and application materials indicating training and sensitivity to research ethics challenges encountered in their work. More than half (52%) identify as ethnic minorities: 22% Black/African American, 11% South Asian, 7% Southeast Asian, 4% Middle Eastern, 4% as Hispanic, and 8% Multiple Ethnicities or Other. Trainees have diverse disciplinary backgrounds in fields including psychology, public health, medicine, anthropology, sociology, and law and held appointments at academic, research, or medical institutions across the United States and internationally. Each year, costs for supporting trainees from institutions outside the United States (South Africa, Kenya, and India) are supplemented by the Santander Universities/Fordham University international scholarship program. Over the course of 4 years, only 3 of the 29 admitted trainees were released from the program because they were unable to complete their MRP proposal or to begin to collect data during their first year.

Program Description and Goals

The RETI has four educational objectives formulated around the premise that training a new generation of HIV/drug abuse scientists in ethical theory, practice, and research design requires a multipronged approach to the four key training and resource areas described below.

Responsible Conduct of HIV/Drug Abuse Prevention Research: Theory and Practice

The summer institute curriculum is designed to enhance knowledge of research ethics theory and practices, current ethical issues, and federal regulations and international guidelines. Table 1 provides examples of learning objectives, which are modified annually by the MAC based on newly emerging ethical issues, trainee and faculty feedback, and the educational needs of each new cohort. The curricula for the 10-day summer training institute for new trainees, the overlapping 5-day advanced seminars for returning trainees, the MRP, and contributions to the online ethics resource platform are designed to address these four key training and resource areas.

Engaging Participants and Communities in the Construction of Research Design and Participant Protections

Federal regulations and international guidelines for participant perspectives are purposely broad to ensure their applicability across diverse and shifting research activities, settings, and populations. Thus, ethical decisions for HIV and drug abuse research require contextually sensitive interpretations of these regulations (Sugarman, Rose, & Metzger, 2014). Engaging in this system of interpretation, investigators draw upon organizational policies, their IRBs, and their own moral compass. However, participants with the psychological, medical, social, and economic vulnerabilities tied to drug abuse and related HIV risk behaviors may not concur with these interpretations (Fisher, 1999, 2004; Melton, Levine, Koocher, Rosenthal, & Thompson, 1988). The views of persons with or at risk of HIV and those who use illicit drugs are thus critical for identifying research practices that may cause participant distress, violate participant privacy, or threaten participant autonomy not readily discerned through professional logic or scientific inference (Fisher, 1999). Participant perspectives can also help investigators and their IRBs avoid rejecting study procedures as harmful, when in fact prospective participants see them posing little if any such risks, and evaluate the benefits as clearly outweighing such risks (Fisher, 2004).

Understanding how to best engage both the communities that host trainees' research as well as the research participants themselves is a key dimension of RETI training. Using lectures, case studies, and group discussions, trainees are introduced to methods on how best to identify appropriate participant and community representatives and convene, collaborate with, and disseminate information to Community Advisory Boards (CABs) in the process of creating knowledge and change. Trainees are introduced to co-learning practices as a means of applying a relational ethics framework to community research and in methods to sustain community and participant engagement throughout the process of data collection, analysis, and interpretation and dissemination (Ahmed & Palermo, 2010; Ali, Hyder, & Kass, 2012; Fantuzzo, McWayne, & Childs, 2006; Fisher, 1999, 2002, 2004, 2014, 2015; Fisher & Ragsdale, 2006; Morin et al., 2008). Putting knowledge into action, trainees are also

Table 1. Examples of Learning Objectives for RETI Curriculum Domains.

HIV/drug abuse research ethics: History, theory, and basic concepts: Increase familiarity with (a) history of HIV/drug abuse ethics controversies (e.g., AZT trials); (b) theoretical moral frameworks guiding HIV/drug abuse research ethics (e.g., Belmont Principles, Health Equity, Social Justice); and (c) HIV/drug abuse relevant research ethics challenges (e.g., preventive misconception, use of placebos)
IRB/REC review of HIV/drug abuse research: Increase (a) familiarity with U.S. regulations and international standards (e.g., CIOMS and WHO); (b) understanding of international differences in responsibilities and procedures of IRBs/RECs; (c) ability to identify and address common ethical questions/challenges of IRB/REC review of HIV/drug abuse prevention research; and (d) ability to identify empirical research area to help inform institutional ethics review
Informed consent to HIV/drug abuse research: Increase skills to (a) understand cognitive and neuropsychological effects of HIV/AIDS and drug use on informed consent; (b) assess developmental, cognitive, health, educational, language, and cultural factors influencing ability of socially vulnerable populations to give informed consent; (c) develop educational procedures to enhance consent readiness for HIV trials involving persons who use drugs including HIV vaccine trials, PrEP adherence studies; (d) assess and provide participant protections under conditions in which waiver of guardian permission is appropriate (e.g., LGBT, homeless youth); and (e) ensuring voluntary consent of adult prisoners, women with limited autonomy, serodiscordant couples, individuals without access to other health services, and other vulnerable populations
Protecting confidentiality and privacy in HIV/drug abuse research: Increase ability to (a) assess and minimize social /legal/economic harms of HIV/drug abuse research recruitment, participation, and dissemination involving vulnerable groups (e.g., participants in countries criminalizing homosexual behavior, women at risk for interpersonal violence, LGBT youth) and (b) identify and develop adequate procedures to protect participant confidentiality when using new technologies (e.g., mHealth, social media).
Standards of prevention and posttrial care in HIV/drug abuse research: Enhance understanding of and ability to develop empirical methods to (a) inform current ethical controversies surrounding designing protocols with sufficient power and control that appropriately incorporate HIV and drug abuse risk reduction packages that meet criteria for standard of care/prevention, (b) develop strategies for provision of care for participants who are HIV seroconvert or experience addiction relapse during trials, and (c) address ethical challenges of posttrial provision of HIV and drug treatments proven effective during the trial
Ethical engagement of communities in HIV/drug abuse research: Increase capacity to (a) identify appropriate community stakeholders; (b) actively engage participants, health and social service providers, and distinct cultural communities in the planning, administration, and evaluation of participant and community protections in HIV/drug abuse research; and (c) address ethical challenges faced by peer trainers and community researchers
Models of ERRE for HIV/drug abuse prevention research: Increase (a) expertise in conceptual frameworks guiding ERRE that can inform normative ethics and ethics norms; (b) competence in the use of established ERRE quantitative and qualitative methods involving vulnerable populations; and (c) to identify and select demographic (e.g., medical history, drug use, sexual orientation), experiential (e.g., health disparities, incarceration, sex work), and psychosocial (e.g., HIV/drug abuse stigma, racial/ethnic discrimination) factors that should be included as independent variables or covariates in research ethics investigations; and (d) to identify areas of ERRE that can inform IRB/REC review

Note. AZT = azidothymidine; LGBT = lesbian, gay, bisexual, and transgender; RETI = Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute; IRB = institutional review board; REC = Research Ethics Committee; CIOMS = Council for International Organizations of Medical Sciences; WHO = World Health Organization; PrEP = pre-exposure prophylaxis; ERRE = empirical research on research ethics.

required to include CABs in the design and interpretation phases of their MRP to ensure that community guidance reflects the values, and merits the trust of those who will be recruited for participation and draw on CAB expertise for wider community dissemination of their MRP results.

Conducting Empirical Research on HIV and Drug Abuse Prevention Research Ethics Practices and Policies

The MRP provides a unique, hands-on opportunity for trainees to work with a faculty expert on an original study aimed at examining an ethical issue that can contribute to evidence-based research. The RETI program provides trainees with intensive mentoring and a small grant of US$18,000 + 8% indirect costs (IDC) to conduct an empirical study that can inform national and international HIV/drug abuse research ethics practices and policies. Prior to arriving at their first summer institute, each trainee has pre-institute conference calls with the institute director and his or her mentor to begin to formulate their MRP topic and methodology and are required to submit a pre-institute literature review and abstract of the proposed research goals and design. During the institute, incoming trainees meet with their mentors a minimum of three times to develop their proposals. Trainees are also introduced to focus group and interview methods that have successfully been employed to engage drug users in discussion about their hopes and concerns regarding research ethics practices (Fisher & Wallace, 2000; Marshall, 1999).

During the latter part of the summer institute, one day is dedicated to presentations by returning trainees on their MRP progress, and the last day of the institute is dedicated to presentations by new trainees on their proposed MRP. The goals of these sessions are (a) to provide new trainees

with models of successful MRP design and implementation; (b) to have all trainees benefit from constructive feedback on their MRPs from faculty and peers; and (c) to provide exposure to a broader range of HIV/drug abuse ethical issues and methodologies. In the fall, following their first summer institute, each trainee submits a draft proposal of their MRP research, an itemized budget (with guidance from the program's budget administrator) and IRB application for review and feedback by the director and their mentor. Once they receive approval on a final proposal, trainees submit their project for IRB approval from their home institution, and following IRB approval, a small grant contract is finalized between the RETI program and their institution. Over the course of 2 years, the trainees receive intensive mentoring from their mentor and feedback from the director, other trainees, and faculty. The RETI director and staff ensure that trainees meet certain benchmarks including monthly conference calls with their mentor; mid-year conference calls with the director; and trainees' progress reports, which are required 6, 12, 18, and 24 months after beginning the MRP.

Creating and Sustaining an Information and Communication Network for Enhancing Ethical Knowledge, Ethical Dialogue, and Professional Collaborations in HIV/Drug Abuse Prevention Research Ethics

Ethical decision making is a dynamic process of constructing best possible procedures within the unique context of each HIV/drug abuse research design. Seasoned investigators discover effective ways to address ethical challenges as they emerge; however, few publicly available resources exist, which enable scientists to share their experiences or access the growing body HIV/drug abuse research ethics publications. Consequently, an important component of the RETI program has been creating and sustaining an online information and communication platform that provides several web-based resources for HIV and drug abuse prevention information and materials, as well as outlets to disseminate the work of RETI trainees and faculty and facilitate future collaborations. These web resources include an extensive, continuously updated bibliography; our recently developed Research Ethics Scales and Measures web page; access to faculty lectures from the summer institute, information on the trainees and their MRPs, and links to international research ethics regulations; and NIH funding opportunities. These globally utilized platforms not only serve those involved with the RETI program but are also designed to be the definitive HIV and drug abuse prevention research ethics resource, providing visitors with access to both the educational materials and research results from the program.

The HIV and Drug Abuse Prevention Research Ethics Resources page housed on the RETI website includes links to the following continuously updated resources: HIV/Drug Abuse Ethics Bibliography (with approximately 500 publications), national and international research ethics regulations and guidelines, downloadable PowerPoint RETI faculty lectures from each year's institute, and links to relevant government and organization resources. In addition, the program developed and implemented the first-of-its-kind Research Ethics Scales and Measures web page, which contains continuously updated published surveys and other testing instruments for investigators who wish to use scales and measures to study HIV, drug abuse, and other research ethics questions. The Fordham University Center for Ethics Education also operates the *Ethics & Society* blog, which routinely features posts on or by RETI trainees and faculty. Finally, the @FordhamEthics Twitter account, which is used to disseminate the work of RETI trainees and faculty, has approximately 830 followers and is continuously expanding the institute's global reach.

Program Evaluation

Formal evaluations for each of the four dimensions of the program are conducted each year via pre- and post-institute surveys, assessment of trainees' progress reports, and monitoring the analytics of the global information platform.

Assessment of Knowledge Gains and Programmatic Achievements

Each year, the incoming cohort takes pre- and post-institute surveys, a comparison of which provides benchmarks to indicate the effectiveness of the curriculum and areas for improvement. Table 2 illustrates the survey categories, exemplar items (all rated on 5-point Likert-type scales), and range of percent post-institute increases in scores each summer across the four cohorts. Incoming and returning fellows and faculty also complete post-institute evaluations on satisfaction with and suggestions for improvement for the summer curriculum, administration of the summer and year-round program, and MRP. Overall, incoming trainees responded positively to curriculum content and reported that MRP-related activities during the institute were helpful and effective in preparing their MRP proposals and increasing their capacity to empirically study research ethics issues, with 83% of trainees agreeing or strongly agreeing that they gained useful knowledge from the institute.

Following each summer institute, all participating faculty members complete a post-institute survey to obtain their input on how to best improve the institute, including the curriculum, facilities, and preparedness and responsiveness of trainees to institute discussions, mentoring, and the

Table 2. Examples of RETI Summer Session Pre–Post Survey Categories, Items, and Range of Percent Improvement Across Trainee Cohorts 1 to 4.

Survey category, number of items, and % improvement range across four cohorts	Item exemplars
National and international regulations and best practice guidelines (12 items), 45%-96%	Federal Regulations; NIDA Policy on Counseling and Testing for HIV/AIDS and Other Infectious Diseases; UNAIDS, Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials; WHO Ethical Considerations in Biomedical HIV Prevention Trials; HPTN Ethics Guidance for HIV Prevention Trials Research
Quantitative and qualitative empirical studies on research ethics in HIV/drug abuse research (12 items), 13%-98%	Participant/community trust/mistrust in HIV/drug abuse research; participant/investigator/IRB attitudes toward monetary compensation for persons who use drugs; procedures for improving informed consent/assent comprehension; confidentiality; strategies for culturally competent research; participant, investigator, IRB attitudes toward emerging technologies for HIV research
Assessing and enhancing informed consent in HIV research (10 items), 41%-86%	Neurocognitive effects of HIV and drug abuse; cultural influences; participants with mental health disorders; prisoners; children and adolescents; web-based, mHealth and social media; increasing research participation literacy
Coercive and noncoercive recruitment and compensation (5 items), 68%-116%	Respondent-driven sampling; recruitment of sex workers with and without "manager's" participation; recruitment of prisoners and parolees; fair monetary compensation; provision of research related and unrelated health care
Confidentiality and disclosure procedures with specific populations (12 items), 32%-118%	Serodiscordant couples; men who have sex with men; women in gender oppressive locales; sex workers; web-based research; LGBT youth; ethnographic research
HIV/drug abuse randomized clinical trials (7 items), 64%-142%	Reducing therapeutic/preventive misconception; appropriately addressing participant mistrust; determining treatment condition equipoise; providing postexperimental services to participants
Engagement of participants and communities in aspects of HIV/drug abuse research (8 items), 14%-64%	Identify stakeholders; engage community in development of research protocols, recruitment and retention plans, implementation, and dissemination; assess participant expectations with respect to research risks, benefits, and impact; protect communities from research-related stigma; increase community benefits
Methods to conduct empirical research on research ethics (14 items), 23%-35%	Assessing and enhancing informed consent capacity; methods for studying effects of local laws on participant protections; qualitative methods for identifying participant attitudes and understanding of research and human subjects protections; studying institutional/ethics review board procedures; using quantitative methods to study individual and contextual factors associated with participant research ethics attitudes and reactions

Note. $n = 27$, except for questions on familiarity with empirical studies on research ethics in HIV/drug abuse research which were added in Year 2 ($n = 19$). RETI = Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute; NIDA = National Institute on Drug Abuse; UNAIDS = United Nations Programme on HIV/AIDS; HPTN = HIV Prevention Trials Network; IRB = institutional review board; WHO = World Health Organization; LGBT = lesbian, gay, bisexual, and transgender.

quality of their MRP presentations. These evaluations have been extremely positive, and the RETI has been highly responsive to faculty recommendations for curriculum improvements. In addition, the director of the institute has yearly conference calls with all mentors to discuss their trainees' MRPs and craft a strategy that best addresses each trainee's individual needs and background. Since the RETI began in 2011, many faculty members have indicated that participating in the program has yielded a number of positive outcomes for them professionally including increasing their knowledge of research ethics; forming a professional network with other members of faculty and the trainees, which has resulted in collaborations on publications, presentations, and grants; being identified as research ethics experts in their respective fields; and having access to the RETI online resources. Providing these opportunities for the RETI faculty is a method of continuously improving the program and attracting top scholars in HIV and drug abuse prevention research.

Assessment of community engagement. To date, all trainees have convened CABs to assist in their developing participant- and

Table 3. Publications Based on RETI Trainees' Mentored Research Projects.

Basta, T. B., Stambaugh, T., & Fisher, C. B. (2015). Efficacy of an educational intervention to increase consent for HIV testing in rural Appalachia. *Ethics & Behavior*, *25*(2), 129-145. (PMCID—In Progress)

Broaddus, M. R., & Marsch, L. (2015). Comparing risks and benefits of text message-delivered and small group-delivered sexual health interventions among African American young women in the Midwestern U.S. *Ethics & Behavior, 25*(2), 146-168. (PMCID—In Progress)

Brown, B., Davtyan, M., & Fisher, C. B. (2015). Peruvian female sex workers' ethical perspectives on their participation in an HPV vaccine clinical trial. *Ethics & Behavior, 25*(2), 115-128. (PMCID—In Progress)

Chiu, C. J., Menacho, L., & Young, S. (in press). The association between age and ethics-related issues in using social media for HIV prevention in Peru. *Ethics & Behavior*.

Curtis, B. (2014). Online recruiting for HIV research: New challenges for institutional review boards. *Journal of Empirical Research on Human Research Ethics, 9*(1), 58-70. (PMID: 24572084; PMC4316828)

Goldenberg, S., Rivera Mindt, M., Jimenez, T. R., Brouwer, K. C., Miranda, S. M., & Fisher, C. B. (2014). Structural and interpersonal benefits and risks of participation in HIV research: Perspectives of female sex workers in Guatemala. *Ethics & Behavior, 25*(2), 97-114. (PMCID—In progress)

Guadamuz, T., Goldsamt, L. A., & Boonmongkon, P. (2014). Consent challenges for participation of young men who have sex with men (YMSM) in HIV prevention research in Thailand. *Ethics & Behavior, 25*(2), 169-184. (PMCID—In Progress)

Kostick, K., Weeks, M., & Mosher, H. (2014). Participant and staff experiences in a peer-delivered HIV intervention with injection drug users. *Journal of Empirical Research on Human Research Ethics, 9*(1), 6-18. (PMID: 24572079. PMC4318632)

Madhivanan, P., Krupp, K., Kulkarni, V., Kulkarni, S., Vaidya, N., Shaheen, R., . . . Fisher, C. B. (2014). HIV testing among pregnant women living with HIV in India: Are private providers routinely violating women's human rights? *BMC International Health and Human Rights, 14*, 7. (PMID: 24656059. PMC3975140)

Pearson, C. R., Parker, M., Fisher, C. B., & Moreno, C. (2014). Capacity building from the inside out: A randomized control trial on adapting the CITI ethics certification training course for American Indian community researchers. *Journal of Empirical Research on Human Research Ethics, 9*(1), 46. (PMID: 24572083. PMC4004423)

Reed, E., Khoshnood, K., Blankenship, K., & Fisher, C. B. (2014). Confidentiality, privacy, & respect: Perspectives of female sex workers participating in HIV prevention research in Andhra Pradesh, India. *Journal of Empirical Research on Human Research Ethics, 9*(1), 19-28. (PMID: 24572080. PMC4111636)

Thokoane, C. (2014). Ethical challenges for piloting sexual health programs for youth in Hammanskraal, South Africa: Bridging the gap between rights and services. *Ethics & Behavior, 25*(2), 185.

Underhill, K. (2013). Study designs for identifying risk compensation behavior among users of biomedical HIV prevention technologies: Balancing methodological rigor and research ethics. *Soc Sci Med*, 94, 115-123. (PMID: 23597916. PMC4047426)

Underhill, K. (2014). Legal issues in addressing participant complaints arising from biomedical HIV prevention trials: How can IRBs respond? *Journal of Empirical Research on Human Research Ethics, 9*(1), 71-82. (PMID: 24572085. PMC4041031)

Urada, L. A., & Simmons, J. (2014). Social and structural constraints on disclosure and informed consent for HIV survey research involving female sex workers and their bar managers in the Philippines. *Journal of Empirical Research on Human Research Ethics, 9*(1), 29-40. (PMID: 24572081. PMC4217476)

Urada, L. A., & Simmons, J. (2014). A collaborative methodology for investigating the ethical conduct of research on female sex workers in the Philippines. *Journal of Empirical Research on Human Research Ethics, 9*(1), 41-45. (PMID: 24572082. PMC4065172)

Note. RETI = Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute.

population-sensitive research designs and implementation. Trainees in our early cohorts who completed data collection have drawn on the wisdom of their CABs for interpretation and dissemination of their MRPs. In so doing, their MRPs have been successful in illuminating the moral lens through which HIV and drug abuse prevention research is viewed by participant populations. The long-term impact of RETI training is witnessed by the incorporation of CABs into trainees' other research projects, as well as in their own teaching and supervision. Most have included participant perspectives as a critical informational resource for identifying new ethical challenges and in constructing evidence-based ethical practices. Several trainees had particularly productive experiences with their CABs and have continued to work with these community members once their MRPs were finished. For example, one RETI trainee who incorporated community-based participatory research (CBPR) methods to adapt the CITI online research ethics training module to best serve the American Indian–Alaska Native (AIAN) populations drew on her MRP as a pilot study to successfully receive funding from National Institute on Minority Health and Health Disparities (NIMHD) for a large-scale extension of this endeavor. A Cohort 2 trainee has continued to use the CAB he originally convened for this MRP for current research projects and routinely seeks the members' input in any new research he undertakes in Peru before moving forward with developing the study protocol.

Assessment of trainees' research. To date, the trainees' MRPs have focused on a wide range of ethics topics that are linked to their active research programs on HIV; sexually transmitted infections (STI); and related drug abuse testing, prevention, and treatment. Topics have included waiver of guardian permission for HIV research involving young MSM, women's autonomy in countries requiring permission of male relatives for HIV treatment, recruitment and confidentiality concerns of FSWs and victims of interpersonal violence, ethical issues in the use of social media and mHealth techniques to reduce HIV risk and substance abuse, participant attitudes toward lack of postexperimental access to Truvada following the completion of a PrEP trial, and IRB processes for handling participant complaints and evaluating research involving new technologies. The MRPs focus on vulnerable populations within the United States (African American, AIAN, Appalachian, and Hispanic populations) and have significant global reach in El Salvador, Guatemala, Peru, Kenya, South Africa, Tanzania, Thailand, India, and the Philippines.

All Cohorts 1 and 2 trainees successfully completed their MRPs within the time allotted and have disseminated their findings through publications or presentations. Similarly, all Cohorts 3 and 4 trainees are in the process of preparing manuscripts and presentations using their MRP data and are on schedule to complete their 2-year traineeship. To date, fellows have given a total of 46 well-received presentations on their MRPs at national and international professional meetings and conferences including the American Psychological Association, American Public Health Association, Center for Study of Addiction, Health Educator's Institute, International AIDS Conference, National Harm Reduction Conference, Public Responsibility in Medicine and Research, Social for Applied Anthropology, and the Society for Behavioral Medicine. The trainees have published a total of 17 articles in journals such as the *BMC International Health and Human Rights, Ethics & Behavior, Journal of Empirical Research on Human Research Ethics*, and *Social Science and Medicine* (see Table 3). A full list of the publications and presentations resulting from MRP research can be found on the RETI website. Although not a specific goal of the program, another indication of the highly effective training of the RETI is that five trainees have been awarded federal grants related to their MRP.

Members of all four cohorts have indicated that the mentoring they receive is one of the most rewarding aspects of the RETI, and with continued guidance from the institute director, their mentors, and faculty, many trainees continue to collaborate professionally with faculty and other trainees once their MRPs are completed. In addition, 89% of trainees from Cohorts 1 to 4 have been identified as experts in research ethics at their home institutions and have taught and guest lectured on the subject. Finally, through annual surveys and conference calls with the director, we have continued to mentor, provide travel support for publication and presentations related to their MRP, assist with ethics relevant grant applications, and evaluate the progress of trainees who have completed their 2-year program.

Assessment of global information platform. To date, the RETI website has seen a steady increase in web traffic since its creation in April 2011, with a total of 38,800 page views, and 15,269 visitors from 150 different countries. The pages containing RETI application information saw nearly 7,000 page views since their creation in 2011. The RETI website continues to be updated and integrated into existing Fordham Center for Ethics Education sites to make it more intuitive, informative, and user-friendly. The *Research Ethics Scales and Measures* webpage has nearly 2,800 views to date, was disseminated through our extensive RETI contact list, and has already been included on several university and organization online resources lists, including the American Anthropological Association, Public Responsibility in Medicine and Research (PRIM&R), the Georgetown Bioethics Research Library, and the Center for Disease Control's quarterly newsletter. Finally, the *Ethics & Society* blog, which routinely features posts on or by RETI fellows and faculty, has accumulated approximately 68,000 views since its creation in May 2013.

Program Impact and Future Activities

The success of research on the development of effective prevention strategies to reduce the transmission and acquisition of HIV/AIDS is dependent upon ethical procedures that reflect the values and merit the trust of research participants and the communities in which research is conducted. At present, ethics is underrepresented in HIV and drug abuse prevention training programs. The RETI has met this urgent need by providing early-career investigators with the skills to identify and address ethical issues, engage communities in the construction and evaluation of population-sensitive research protections, and generate empirical data to inform ethical practice and policies for HIV prevention science.

The impact of the RETI and need for other such programs has been demonstrated in the enthusiasm with which internationally recognized experts in the field have participated as faculty and mentors, the publication of completed MRPs in prominent research ethics journals, and the extent to which national and international organizations, including PRIM&R, the flagship organization for IRBs, have accepted and invited RETI trainees to report on their work. In addition, the global interest in empirical data and other resources on HIV/drug abuse prevention research ethics is evidenced by the increasing number of national and international views and downloads of the RETI online resources. Continued dissemination of empirical data generated by MRPs to scientists, IRBs, and community stakeholders will

build the evidence-base essential to ensure that HIV/drug abuse research ethics policies and practices effectively address the unique health and human rights needs of affected populations.

Curriculum Monitoring and Modification

Given the successful completion at every step, it is the teamwork among program staff, mentors, and faculty who have made this a highly successful program and go beyond the individual characteristics of those who applied. The program's hands-on approach has been cited by both trainees and faculty members as a major strength, and something that other training institutes do not do. We follow up constantly with trainees, require progress reports every 6 months, and encourage monthly phone calls between mentors and mentees. By creating an intensive interactive program that is the result of a committed program director, staff, mentors, and faculty, we have had success with all individuals in the program. We have found that our biggest challenge is the frequently slow response time from university IRBs and budget offices. Based on these experiences, we have over the years increased our familiarity with the requirements of trainees' IRBs and developed relationships with their institutional research offices early in the training process.

Building on these successes, updating of the program in response to trainee and faculty feedback and emerging issues in the field will continue to strengthen and expand its impact. Each spring, the MAC guides the modification of the summer institute curriculum to identify retention and changes in format, content, and teaching styles that meet specific aims of the training program and those that need improvement. The MAC also makes curriculum modifications based on emerging ethical issues in the field, results of the post-institute surveys, and yearly availability of faculty. For example, based on post-institute evaluations, we have added more time during the institute to work on the MRP, included new peer-mentoring sessions, increased coverage of research ethics involving new technologies, provided more targeted instruction in research ethics methods, highlighted specific health and human rights needs of persons who use drugs, and increased yearly planning and debriefing calls with faculty and mentors. The curriculum will continue to evolve to incorporate additional training in the unique ethical issues arising in combined HIV and drug abuse interventions and the continuing evolution of new technologies used in HIV and drug abuse prevention research (i.e., data security with online surveys and using mobile devices in data collection). The dynamic nature of our program development situates the RETI at the forefront of this evolving and increasingly integral part of research ethics, attracting both trainees and faculty who wish to keep abreast of the most recent ethical issues.

Educational Implications

Few graduate and postgraduate programs in the social behavioral, public health, and medical sciences provide faculty with skills to mentor and integrate into their curricula training in HIV/drug abuse prevention research ethics. Since the creation of the RETI, a long-term objective has been to promote and encourage the incorporation of research ethics as a standard component of doctoral and postdoctoral research training programs. While the RETI, along with a few other pioneering programs—mostly international—have provided the materials and resources necessary to include research ethics and methods of studying research on research ethics, these resources and curricula must now be widely adapted (Kalichman, 2009). The results of the RETI pre-institute surveys indicate that a small minority of the 116 applicants had any research ethics training beyond the CITI online module. As a result, we recommend that at least one course, including those focused on research design, should include how to incorporate research on research ethics into their major research procedures.

The RETI provides a resource for the development of other programs by providing public access to the institute's downloadable faculty lectures. We are also introducing a new initiative that provides public Internet access to video lectures and podcasts and creating and sustaining downloadable educational modules for seasoned professionals and graduate and postgraduate faculty. Another new feature the RETI is developing is a live webinar on mentoring the conduct of empirical research on HIV/drug abuse research ethics. Through these materials, the RETI program ensures that it is not only preparing a select group of trainees, but also providing the materials and means for others throughout the world to benefit from these unique, specialized training resources.

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Author Biographies

Celia B. Fisher is the director of the Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute, the Marie Ward Doty Endowed University Chair, founding director of the Fordham University Center for Ethics Education, and professor of psychology. Her current projects include sexual health research ethics, health disparities, and research ethics training. She is responsible for the content and writing of the article, including conception and design, analysis, and interpretation of data.

Elizabeth Yuko is the program administrator for the HIV and Drug Abuse Prevention Research Ethics Training Institute at the Center for Ethics Education at Fordham University. Her current projects include research ethics in HIV-drug abuse research and sexual health and reproductive ethics. She is responsible for writing the content resulting from the program's formal evaluation, along with the design and implementation of the global information platform.